

REMARKS

Reconsideration and allowance are respectfully requested.

Claims 28-30, 32, 34-42, 44, 46-56, 58-67 and 71-72 are pending.

The amendments are fully supported by the original disclosure and, thus, no new matter is added by their entry. Support for the amendment to claim 28 can be found, *inter alia*, in original claims 31 and 33. Support for the amendment to claim 40 can be found, *inter alia*, in original claims 43-45. Support for the amendment to claim 52 can be found, *inter alia*, in original claim 57 and the specification at page 15, lines 2-16, and page 20, lines 23-26 (see also lines 28-31). Support for the amendment to claim 53 can be found, *inter alia*, in original claim 57 and the specification at page 15, lines 2-16, and page 21, lines 7-10 (see also lines 20-22). Claims 40 and 52 remain directed to *in vivo* treatments so "to said culture" is deleted. A misspelling in claim 51 is corrected. The subject matter of amended claims 52-53 is related to p53-deficient microorganisms and alopecia, respectively, and support for washing of at least 3 hours is found on page 15, first full paragraph, of the specification.

Entry of the amendments is requested to address the remaining obviousness rejection. Entry of the claim amendments will reduce the issues on appeal and do not require additional search or consideration.

35 U.S.C. 103 – Nonobviousness

To establish a case of prima facie obviousness, all of the claim limitations must be taught or suggested by the prior art. See M.P.E.P. § 2143.03.

Claims 28-32, 35-44, 47-67 and 71-72 were rejected under Section 103(a) as allegedly unpatentable over Fondy et al. (EP 0297946) in view of Richman et al. (J. Biol. Resp. Mod. 9:570-575, 1990) taken together with Lane et al. (WO 94/12202). Applicants traverse because the Examiner has indicated that the subject matter of claims 33 and 45 (e.g., washing for a time greater than or equal to 3 hours). Therefore, incorporation of this limitation in claims in the independent claims directed to methods of treatment should result in allowance of claims 28-30, 32, 34-42, 44, 46-56 and 71-72.

As to the pharmaceutical compositions of claims 58-62, they are retarded release compositions, characterized by the fact that the release of the protective compound occurs immediately while the delivery of the chemotherapeutic compound is retarded. The claims are supported at page 23, lines 1-5, of the specification. Such pharmaceutical compositions represent tools to practice the claimed medical treatment.

The person skilled in the art of formulating pharmaceutical compositions is well aware of the many known methods for preparing compositions suitable for a controlled delivery of different active agents in different times. By way of example only, a composition having only protective compound A, coated by a controlled release layer also comprising a mixture of protective compound A and chemotherapeutic compound B, coated again by another layer comprising only protective compound A would give raise to a release profile corresponding to the different stages of the claimed method.

None of the cited references teaches or suggests such a composition. Therefore, claims 58-62 are patentable because there is no evidence showing one of ordinary skill in the art would have been motivated to make the retarded release compositions of the claims.

Also the kit of parts according to claims 63-67 is characterized by the fact that the different components are intended for sequential administering to a patient in order to reproduce the different phases of the claimed method of treatment. None of the cited references teaches or suggests such an object. Accordingly, claims 63-67 are patentable because there is no evidence showing one of ordinary skill in the art would have been motivated to sequentially administer the different components of the claims.

Withdrawal of the Section 103 rejection is requested because the invention as claimed would not have been obvious to a person of ordinary skill in the art at the time it was made.

Conclusion

Having fully responded to all of the pending objections and rejections contained in this Office Action, Applicants submit that the claims are in condition for allowance and

earnestly solicit an early Notice to that effect. The Examiner is invited to contact the undersigned if any further information is required.

Respectfully submitted,

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